IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG, NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD., and PROTERRA AG, Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	**FILED ELECTRONICALLY** Civil Action No.: 06045 (RMB)
DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Counterclaim Plaintiffs, v. NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG, NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD., and PROTERRA AG, Counterclaim Defendants.	

ANSWER AND COUNTERCLAIM
OF DR. REDDY'S LABORATORIES, LTD. AND
DR. REDDY'S LABORATORIES, INC.

Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (respectively, "DRL, Ltd." and "DRL, Inc.", collectively, "Defendants" or "DRL") by their attorneys, for their answer to the complaint by Plaintiffs Novartis Pharmaceuticals Corporation ("NPC"), Novartis AG, Novartis Pharma AG, Novartis International Pharmaceutical Ltd. ("NIP"), and Proterra AG (collectively "Plaintiffs" or "Novartis") in the above-captioned matter, respond as follows:

NATURE OF ACTION

1. As to paragraph 1 of the complaint, DRL admits that Plaintiffs have styled this action as one for patent infringement.

THE PARTIES

2. DRL lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the complaint.

3. DRL lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 of the complaint.

4. DRL lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4 of the complaint.

5. DRL lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 5 of the complaint.

6. DRL lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 6 of the complaint.

7. DRL admits the allegations of paragraph 7 of the complaint.

8. DRL denies the allegations of paragraph 8 of the complaint and states that DRL, Inc. has its office and principal place of business at 200 Somerset Corporate Building, 7th Floor, Bridgewater, New Jersey 08807.

9. DRL admits the allegation of paragraph 9 of the complaint.

10. DRL denies the allegations contained in paragraph 10 of the complaint.

11. DRL denies the allegations contained in paragraph 11 of the complaint, except that DRL admits that DRL, Inc. is the initial contact and liaison for the licensing of products developed by DRL, Ltd. as part of its research and development efforts.

12. Paragraph 12 of the Complaint contains no allegation requiring affirmation or denial. DRL acknowledges that for purposes of the Complaint, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Ltd. are referred to collectively as "DRL."

JURISDICTION AND VENUE

13. DRL admits the allegations in paragraph 13 of the complaint.

14. DRL denies the allegations contained in paragraph 14 of the complaint, except DRL admits that DRL, Inc. and DRL, Ltd. are subject to personal jurisdiction within this judicial district.

15. DRL admits the allegation in paragraph 15 of the complaint.

CLAIM FOR RELIEF: PATENT INFRINGEMENT

16. DRL incorporates by reference its answers in paragraphs 1-15 herein.

17. On information and belief, DRL admits the allegations of paragraph 16 of the Complaint.

18. DRL lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 17 of the Complaint.

19. DRL denies the allegations of paragraph 18 of the Complaint except that, on information and belief, DRL admits that United States Letters Patent No. 4,948, 807 ("the '807 patent") was issued on August 14, 1990 and that Proterra AG purports to own the '807 patent.

20. As to the first sentence of paragraph 19 of the Complaint, DRL denies the allegations contained therein and states that claim construction is a question of law for the Court. As to the second sentence of paragraph 19 of the Complaint, DRL admits that what appears to be a copy of the '807 patent is attached to the complaint as Exhibit A.

21. DRL denies the allegations of paragraph 20 of the Complaint, except that DRL admits that Novartis AG purports to own United States Letters Patent No. 5,602, 176 ("the '176 patent") and that the '176 patent was issued on February 11, 1997.

22. DRL admits that an assignment of the '176 patent to Sandoz Ltd. was recorded with the United States Patent and Trademark Office ("PTO"). As to the remaining allegations of paragraph 21 of the Complaint, DRL lacks knowledge or information sufficient to form a belief as to the truth of those allegations.

23. As to the first sentence of paragraph 22 of the Complaint, DRL denies the allegations contained therein and states that claim construction is a question of law for the Court. As to the second sentence of paragraph 22 of the Complaint, DRL admits that what appears to be a copy of the '176 patent is attached to the Complaint as Exhibit A.

24. DRL admits the allegations of paragraph 23 of the Complaint.

25. DRL admits the allegations of paragraph 24 of the Complaint.

26. DRL denies the allegations of paragraph 25 of the Complaint, except that DRL admits that the filing of a Paragraph IV certification in connection

with an ANDA is a technical act of infringement under 35 U.S.C. § 271(e)(2)(A).

27. DRL admits the allegations in paragraph 26 of the Complaint.

28. DRL denies the allegations in paragraph 27 of the Complaint, except that DRL admits that it filed an ANDA seeking approval to manufacture and sell its rivastigmine tartrate 1.5 mg, 3 mg, 4.5 mg and 6 mg capsules.

29. DRL denies the allegations in paragraph 28 of the Complaint.

30. DRL denies the allegations in paragraph 29 of the Complaint except that DRL admits that it was aware of the '807 and '176 patents when DRL filed its ANDA and admits that its filing of a Paragraph IV certification in connection with its ANDA on rivastigmine tartrate is a technical act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER TO PRAYER FOR RELIEF

DRL denies that plaintiffs are entitled to the judgment and relief prayed for in paragraphs (A) through (F) under the heading "Prayer for Relief" in the Complaint.

FIRST AFFIRMATIVE DEFENSE

31. Claims 1-6 of the '176 patent are invalid for obviousness under 35 U.S.C. § 103.

SECOND AFFIRMATIVE DEFENSE

32. Claims 3 and 4 of the '807 patent are invalid for obviousness under 35 U.S.C. § 103.

THIRD AFFIRMATIVE DEFENSE

33. Claims 1-3 of the '176 patent are invalid under 35 U.S.C. § 102(b).

FOURTH AFFIRMATIVE DEFENSE

34. Claims 1-4 of the '807 patent are invalid under 35 U.S.C. §§ 101 and 112 for lack of utility, lack of enablement, inoperability and inadequacy of written description.

FIFTH AFFIRMATIVE DEFENSE

35. Each and every claim of the '176 patent is invalid under 35 U.S.C. §§ 101 and 112 for lack of utility, lack of enablement, inoperability and inadequacy of written description.

SIXTH AFFIRMATIVE DEFENSE

36. Each and every claim of the '176 patent is invalid and unenforceable under the doctrine of prosecution laches.

WHEREFORE, DRL prays for relief as follows:

(a) That the Complaint against it be dismissed with prejudice;

(b) That this case be deemed an "exceptional case" within the meaning of 35 U.S.C. § 285;

(c) That DRL be awarded its attorneys fees, expert fees and costs of suit; and

(d) That the Court award such other and further relief as this Court may deem just and proper.

COUNTERCLAIMS

Counterclaim Plaintiffs Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc., (respectively, "DRL Ltd." and "DRL, Inc." and collectively, "DRL"), for their Counterclaim against Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma, and Proterra AG, (collectively "Novartis" or "Counterclaim Defendants"), allege and aver as follows:

THE PARTIES

1. Counterclaim Plaintiff DRL, Ltd. is an Indian public limited liability company incorporated and existing under the laws of India and having a principal place of business at 7-1-27, Ameerpet, Hyderabad 500 016, India.

2. Counterclaim Plaintiff DRL, Inc. is a New Jersey corporation, having its principal place of business at 200 Somerset Corporate Blvd., 7th Floor, Bridgewater, New Jersey 08807. DRL, Ltd. and DRL, Inc. are collectively referred to herein as "DRL."

3. On information and belief, Plaintiff/Counterclaim Defendant Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, Hanover, New Jersey 07396.

4. On information and belief, Plaintiff/Counterclaim Defendant Novartis International Pharmaceuticals, Ltd. ("NIP") is a corporation organized and existing under the laws of Bermuda, having an office and place of business at Hurst Holme, 12 Trott Road, Hamilton HM LX, Bermuda.

5. On information and belief, Plaintiff/Counterclaim Defendant Novartis AG ("Novartis AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

6. On information and belief, Plaintiff/Counterclaim Defendant Novartis Pharma ("Pharma AG") is a corporation organized and existing under

the laws of Switzerland, having an office and principal place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

7. On information and belief, Plaintiff/Counterclaim Defendant Proterra AG is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Postrasse 9, CH-6300 Zug, Switzerland.

JURISDICTION AND VENUE

8. This is an action for a declaratory judgment, together with such further relief based thereon as may be necessary or proper, pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. The basis for a declaratory judgment is, as fully appears below, an actual controversy between DRL and Novartis arising under the United States Patent Laws, Title 35 of the United States Code. This Court has subject matter jurisdiction over the action based on 28 U.S.C. §§ 1331 and 1338.

9. This Court has personal jurisdiction over the Counterclaim Defendants in that, *inter alia*, the Counterclaim Defendants voluntarily filed the complaint in this Court to which this Counterclaim is directed.

10. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(c) and 1400(b).

THE ACTUAL CONTROVERSY
CONCERNING THE '807 AND '176 PATENTS

11. On information and belief, Counterclaim Defendant NPC holds an approved New Drug Application for rivastigmine tartrate, currently marketed under the brand name Exelon®.

12. DRL, as an applicant for an Abbrieviated New Drug Application ("ANDA") for rivastigmine tartrate tablets, is required to make certifications with respect to patents owned or licensed by the NDA holder and which are published in the FDA's Approved Drug Products With Therapeutic Equivalence Evaluations ("the Orange Book"), relating to NPC's rivastigmine tartrate tablet product (hereinafter, "the Novartis product").

13. There are at least two United States Patents that are listed in the Orange Book or Electronic Orange Book (www.fda.gov/cder/ob/default.htm) for the Novartis product, including United States Patent No. 4,948,807 (the "'807 patent"), and United States Patent No. 5,602,176 (the "'176 patent").

14. On information and belief, Counterclaim Defendant Proterra AG purports to be the owner of the '807 patent and Counterclaim Defendant NPC purports to be the exclusive licensee of that patent. On information and belief, the Counterclaim Defendant Novartis AG purports to be the owner of the '176 patent.

15. Counterclaim Plaintiffs DRL submitted to the FDA an ANDA ("DRL's ANDA") under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of its rivastigmine tartrate tablet product (the "DRL Rivastigmine Product").

16. DRL's ANDA included a Paragraph IV certification certifying that, in its opinion and to the best of its knowledge, the '807 patent and the '176 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the DRL's Rivastigmine Product.

17. DRL provided Counterclaim Defendants NPC, Novartis Pharma AG and Proterra AG with written notice of the factual and legal basis supporting its Paragraph IV Certification (the "Notice Letter").

18. After receiving the Notice Letter, the Counterclaim Defendants filed the present action against DRL on August 4, 2004 alleging infringement of the '807 and '176 patents.

19. Based on the facts set forth above in paragraphs 11-19, an actual and justiciable controversy exists among the parties to this action regarding whether there is any valid claim of the '807 or '176 patents that could be infringed by the manufacture, use and/or sale of the DRL Rivastigmine Product, and whether Counterclaim Defendants have the legal right to temporarily, preliminary and

permanently enjoin DRL from manufacturing, using, selling and importing into the U.S. the DRL Rivastigmine Product. DRL requires an immediate declaration of its rights vis-à-vis the Counterclaim Defendants with respect to the '807 and '176 patents.

FIRST CLAIM FOR RELIEF

Declaratory Judgment of Noninfringement Of the '807 Patent and the '176 Patent

20. DRL repeats and realleges the averments of paragraphs 1-19 as if fully set forth herein.

21. DRL seeks a declaration that claims 1-4 of the '807 patent and claims 1-12 of the '176 patent are not infringed and will not be infringed -- either directly, contributorily, or by inducement -- by the commercial manufacture, marketing or sale of DRL's Rivastigmine Product.

SECOND CLAIM FOR RELIEF

Declaratory Judgment of Invalidity of Claims 3-4 of the '807 Patent and All Claims of the '176 Patent Under § 103

22. DRL repeats and realleges the averments of paragraphs 1-19 as if fully set forth herein.

23. DRL seeks a declaration that claims 3 and 4 of the '807 patent and claims 1-6 of the '176 patent are invalid under 35 U.S.C. § 103 based on obviousness.

THIRD CLAIM FOR RELIEF

Declaratory Judgment of Invalidity the '807 Patent and the '176 Patent Under §§ 101 and 112

24. DRL repeats and realleges the averments of paragraphs 1-19 as if fully set forth herein.

25. DRL seeks a declaration that each and every claim of the '807 patent and of the '176 patent is invalid under 35 U.S.C. §§ 101 and 112, for lack of utility, lack of enablement, inoperability and inadequate written description.

FOURTH CLAIM FOR RELIEF

Declaratory Judgment of Invalidity of the '176 Patent Under § 102(b)

26. DRL repeats and realleges the averments of paragraphs 1-19 as if fully set forth herein.

27. DRL seeks a declaration that claims 1-3 of the '176 patent are invalid under 35 U.S.C. § 102(b).

FIFTH CLAIM FOR RELIEF

Declaratory Judgment of Invalidity and Unenforceability of the '176 Patent Under the Doctrine of Prosecution Laches

28. DRL repeats and realleges the averments of paragraphs 1-19 as if fully set forth herein.

29. DRL seeks a declaration that each and every claim of the '176 patent is invalid and unenforceable under the doctrine of prosecution laches.

WHEREFORE, DRL respectfully requests that this Court:

(a) Declare that claims 1-4 of the '807 patent and claims 1-12 of the '176 patent are not infringed and will not be infringed by the commercial manufacture, marketing and/or sale of DRL's Rivastigmine Product;

(b) Declare that each and every claim of the '807 patent is invalid

(c) Declare that claims 1-6 of the '176 patent are invalid;

(d) Declare that each and every claim of the '176 patent is unenforceable.

(e) Adjudge that this case is an "exceptional case" within the meaning of 35 U.S.C. § 285;

(f) Award DRL its attorneys fees, expert fees, and costs of suit; and

(g) Award DRL such other and further relief as this Court may deem just and proper.

Respectfully submitted,

Dated: October 1, 2004

/s

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CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of October, 2004, the Answer and Counterclaim of Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. to Plaintiffs' Complaint was served upon the following counsel via Federal Express:

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/s
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